

EXPRESS MAIL LABEL NO.: EV578080668US

PATENT

Attorney Docket No. 31242-701.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application)	<u>PATENT APPLICATION</u>
)	
Inventor(s): Elizabeth Moyer et al.)	
)	Art Unit: 1645
Serial No.: 09/393,590)	
)	Examiner: DEVI, S.J.N.
Filed: September 9, 1999)	
)	Confirmation No.: 2967
Title: STABLE LIQUID FORMULATIONS)	
OF BOTULINUM TOXIN)	
)	

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

- ☐ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage
-- OR --
- ☐ (3) It is being filed before the mail date of the first Office Action on the merits
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☒ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- ☒ a certification as specified in §1.97(e) is provided below; **or**
- ☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
- B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
- C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☒ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.), copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).

☐ Attached are the following non-published pending patent applications which may be deemed relevant.

☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.31242-701.201).

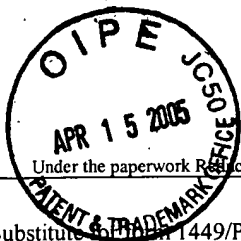
Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: April 15, 2005

By: Albert P. Halluin
Albert P. Halluin
Registration No. 25,227

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971



Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

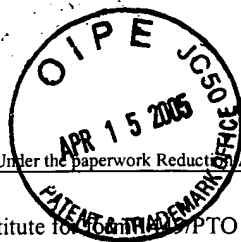
Substitution of Paper 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	09/393,590
				Filing Date	09/09/1999
				First Named Inventor	Elizabeth Moyer
				Art Unit	1645
				Examiner Name	Devi, S.J.N.
Sheet	1	of	3	Attorney Docket Number	31242-701.201

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		6,113,915	09-05-2000	Kei Roger Aoki et al	
		6,139,845	10-31-2000	Stephen Donovan	
		6,350,455 B1	02-26-2002	Stephen Donovan	
		6,358,513 B1	03-19-2002	Martin A. Voet et al	

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
		HENRY S. SACKS ET AL, <i>Clostridium botulinum</i> Type E Toxin: Effect of pH and Method of Purification on Molecular Weight, Applied Microbiology, September 1974, p. 374-382, Vol. 28:3, American Society for Microbiology, USA		
		IWAO OHISHI ET AL, Purification of <i>Clostridium botulinum</i> Type F Progenitor Toxin, Applied Microbiology, December 1974, p. 923-928, Vol. 28:6, American Society for Microbiology, USA		
		IWAO OHISHI ET AL, Molecular Construction of <i>Clostridium botulinum</i> Type F Progenitor Toxin, Applied Microbiology, April 1975, p. 444-447, Vol. 29:4, American Society for Microbiology, USA		
		SHUNJI SUGII ET, Correlation Between Oral Toxicity and In Vitro Stability of <i>Clostridium botulinum</i> Type A and B Toxins of Different Molecular Sizes, Infection and Immunity, June 1977, p. 910-914, Vol. 16:3, American Society for Microbiology, USA		
Examiner Signature			Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

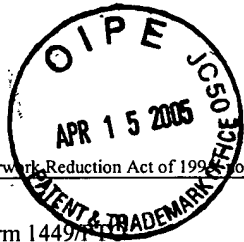
Under the Paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	09/393,590
				Filing Date	09/09/1999
				First Named Inventor	Elizabeth Moyer
				Art Unit	1645
				Examiner Name	Devi, S.J.N.
Sheet	2	of	3	Attorney Docket Number	31242-701.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		IWAO OHISHI ET AL, Activation of Botulinum Toxins in the Absence of Nicking, Infection and Immunity, August 1977, p. 402-407, Vol. 17:2, American Society for Microbiology, USA	
		ALBERT L. LEHINIGER, The Molecular Basis of Cell Structure and Function, Biochemistry (Second Edition), July 1978, 45-50, Worth Publishers, Inc., New York, USA	
		IWAO OHISHI ET AL, Oral Toxicities of <i>Clostridium botulinum</i> Type C and D Toxins of Different Molecular Sizes, Infection and Immunity, May 1980, p. 303-309; Vol. 28:2	
		IWAO OHISHI ET AL, Purification and Characterization of Two Components of Botulinum C ₂ Toxin, Infection and Immunity, December 1980, p. 668-673, Vol. 30:3	
		LEON LACHMAN, Ph.D. ET AL, The Theory and Practice of Industrial Pharmacy, third edition, 1986, p. 458-460, Lea & Febiger, Philadelphia, USA	
		FLORA CHEN ET AL, Biophysical Characterization of the Stability of the 150-Kilodalton Botulinum Toxin, the Nontoxic Component, and the 900-Kilodalton Botulinum Toxin Complex Species, Infection and Immunity, June 1988, p. 2420-2425, Vol. 66:6, American Society for Microbiology, USA	
		J. MELLING ET AL, Clostridium Botulinum Toxins: Nature and Preparation for Clinical Use; Eye, 1988:2, p. 16-23	
Examiner Signature			Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/1-1 INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	09/393,590
				Filing Date	09/09/1999
				First Named Inventor	Elizabeth Moyer
				Art Unit	1645
				Examiner Name	Devi, S.J.N.
Sheet	3	of	3	Attorney Docket Number	31242-701.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		J. HALOUZKA ET AL, Effect of pH on the Stability of Type-C Toxin of <i>Clostridium botulinum</i> , Folia Microbiol, 1992, p. 157-158, Vol. 37:2,	
		GIAMPIETRO SCHIAVO ET AL, Botulinum G Neurotoxin Cleaves VAMP/ Synaptobrevin at a Single Ala-Ala Peptide Bond, The Journal of Biological Chemistry, August 12, 1994, p. 20213-20216, Vol. 269:32, The American Society for Biochemistry and Molecular Biology, Inc., USA	
		ROSSELLA PELLIZZARI ET AL, Structural Determinants of the Specificity for Synaptic Vesicle-associated Membrane Protein/Synaptobrevin of Tetanus and Botulinum Type B and G Neurotoxins, The Journal of Biological Chemistry, August 1996, p. 20353-20358, Vol. 271:34, The American Society for Biochemistry and Molecular Biology, Inc., USA	
		KAY MCLELLAN ET AL, Therapeutic Botulinum Type A Toxin: Factors Affecting Potency, Toxicon, 1996, p. 975-985, Vol. 34:9, Elsevier Science Ltd, Great Britain	
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.